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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,748	11/25/2003	Yasuhisa Fukui	49618DIV(71965)	3389

7590 10/16/2007

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EXAMINER	
GRUN, JAMES LESLIE	
ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
10/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/723,748	FUKUI ET AL.	
	Examiner	Art Unit	
	James L. Grun	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1-17 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/518,737.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/25/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's election of Group II, claims 18 and 19, in the paper filed 31 July 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1-17 and 20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

The disclosure is objected to because of the following informalities: the brief description of drawings 7 and 8, and all reference to said drawings in the specification must indicate the panel of the Figure which is described or to which the reader is being referred, e.g. the Figures should be described and cited as Fig. 8A or Fig. 8B, etc., or Figs. 8A-8H; page 10, line 4, --bisphosphate-- is misspelled. Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, and failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

Claims 18 and 19 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicant defines and exemplifies specificity of an antibody to phosphatidylinositol-3,4-bisphosphate as that which can distinguish phosphatidylinositol-3,4-bisphosphate from other phosphorylated compounds. The specification does not reasonably provide description of or enablement for any and every antibody population specific for phosphatidylinositol-3,4-bisphosphate other than antibody 8C2-FNL, produced by the hybridoma cell line deposited as FERM-BP-6849. Applicant provides guidance only for the above noted monoclonal antibody and provides no guidance as to what modifications or structure are important for the predictable function of any other antibody. Very different structures may be found on antibodies with the same specificity. For example, very different V_H chains can combine with the same V_L chain to produce antibody binding sites with nearly the same size, shape, antigen specificity, and affinity. A similar phenomenon can also occur when different V_H sequences combine with different V_L sequences to produce antibodies with very similar properties. These observations indicate that divergent variable region sequences, both in and out of complementarity-determining regions, can be folded to form similar binding site contours, which result in similar immunochemical characteristics. Conversely, similar structure may be found on antibodies having different specificities. In the absence of any guidance other than to the use of the antibodies produced by the hybridoma cell line deposited as FERM-BP-6849, one would not know or be able to predict or envision what other structure or modifications were important for function. Therefore,

conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that a molecule is part of the invention and a reference to a potential method of isolating it. The molecule itself is required. Furthermore, In *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement that defines a genus of molecules by only their functional activity does not provide an adequate written description of the genus. The court indicated that while applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of molecules falling within the scope of the claimed genus. Applicant is reminded that the written description provision of 35 USC 112, first paragraph, is severable from its enablement provision. However, in view of the guidance in the instant specification to a single species, the amount of experimentation required to determine functional structures or modifications for other usable species would also be undue. For example, as noted above, very different structures may be found on antibodies with the same specificity, and conversely, similar structure may be found on antibodies having different specificities and one would not know, given the instant guidance and absent further unguided experimentation, what variable region changes would predictably function in the invention other than those possessing both the intact V_H and V_L chains of the 8C2-FNL antibody. Note that an enabling disclosure for the preparation and use of only one or a few analogs of a product does not enable all possible analogs where the characteristics of the analogs are unpredictable. See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.* (18 USPQ 2d 1027 (CAFC 1991)).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18 and 19 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 18 and 19, it is believed that either --bisphosphate-- or --diphosphate-- was intended.

In claim 18, "the" antibody and binding lack antecedent basis. It is not clear how one performs the method "based on" an immunological reaction or what is intended as encompassed. The purpose of the method also is not clear as it is not clear what is being detected because in the method antibody is merely reacted with bisphosphate present in the sample.

Claim 19 should recite --The-- immunoassay method for proper reference to the previously recited claim components. In this claim "the" degree lacks antecedent basis.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18 and 19 are rejected under 35 U.S.C. § 102(b) as being anticipated by Boronenkov et al. (Molecular Biol. Cell 9: 3547, 1998).

Boronenkov et al. teach an immunoassay in which phosphatidylinositol-3,4-bisphosphate-containing liposomes specifically inhibit staining with the AM-212 monoclonal antibody elicited to phosphatidylinositol-4,5-bisphosphate.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Miyazawa et al. (Mol. Immunol. 25: 1025, 1988) elicited monoclonal antibodies, the AM-212 monoclonal antibody in particular, by immunization with phosphatidylinositol-4,5-bisphosphate-coated *Salmonella minnesota.*

Any of Thum et al. (Tetrahedron Lett. 37: 9017, 1996), Sawada et al. (Chem. Pharm. Bull 45: 1521, 1997), or Shirai et al. (Tetrahedron Lett. 39: 9485, 1998) teach methods for synthesis of phosphatidylinositol-3,4-bisphosphate and teach or suggest the role of the compound in intracellular signaling.

The art made of record and not relied upon is considered pertinent to applicant's disclosure.

Yokogawa et al (FEBS Lett. 473: 222, 2000) teach the invention essentially as disclosed and claimed.

Fukui et al. (US 6,709,833) claim the FERM-BP-6849 hybridoma.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

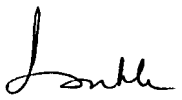
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JLG/
James L. Grun, Ph.D.
October 9, 2007



LONG V. LE 10/11/07
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